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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SCHMICKEL
EXAMINER

FOLEY AND LARDNER, SCHWARTZ, JEFFERY,
SCHWAAB, MACK, BLUMENTHAL AND EVANS
P.O. BOX 299
ALEXANDRIA, VA 22313-0299

1814	ART UNIT	PAPER NUMBER
	01/28/92	7

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-26 are pending in the application.

   Of the above, claims 8-26 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-7 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1814.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, drawn to urate oxidase, classified in Class 435, subclass 191.

II. Claims 8-26, drawn to DNA vectors and methods of producing proteins, classified in Class 435, subclass 69.1.

The inventions of urate oxidase of group I are patentably distinct chemical species from those of group II, DNA sequences, although related in that the DNA sequences encode the urate oxidase. The protein can be isolated from natural sources, and the DNA has utility other than coding for the protein such as a molecular weight marker in PAGE.

Because these inventions are distinct for the reasons given above and have attained a different status in the art as indicated by their different classification. Therefore, a search for each invention is not coextensive an constitutes an undue burden on the examiner and restriction for examination purposes as indicated is proper.

During a telephone conversation with Steve Brent on Dec. 18, 1992 a provisional election was made with traverse to prosecute the invention of group I the urate oxidase, claims 1-7.

Affirmation of this election must be made by applicant in responding to this Office action. Claims 8-26 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The drawings are objected to because of the reasons stated on the PTO-948. Correction is required.

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term 'units' is not defined in the claims. The lack of a definition of the term 'units' renders the concentration indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to teach how to make or use the invention, i.e. failing to provide an enabling disclosure.

All proteins that have a substantial homology to the urate oxidase of the first claim are not enabled by the disclosure. The disclosure of a single species of urate oxidase is inadequate to claim all proteins that have a substantial homology to the disclosed species.

The disclosure does not enable a protein that migrates to 33.5 kDa in all bidirectional gels. Bidirectional gel can be Laemmli/SDS-Urea, Laemmli/SDS-Triton, Laemmli/SDS-Agarose, Laemmli/SDS-Acid/urea/triton, and nurmerous others. The disclosure of the migration of the protein to a spot at 33.5 kDa on a single bidirectional gel does not enable a protein that migrates at 33.5 kDa on any bidirectional gel.

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term preferably renders the claim indefinite.

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

The phrase "a drug containing" is confusing and is objected to. This objection can be obviated by the replacement of that phrase with "a phamaceutical composition comprising".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Laboureur et al.

Laboureur et al. teach the purification of urate oxidase from Aspergillus flavus (A. flavus) and the medical use of the enzyme.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this

section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Laboureur et al.

Laboureur et al. teach as above.

It would have been obvious to one of ordinary skill in the art to further purify the urate oxidase by conventional methods to obtain a protein of the instant invention, and use that protein as a drug.

This would have been motivated by the desire to produce an enzyme with potentially fewer harmful contaminants, and the knowledge that urate oxidase has medical uses as is well known to one of ordinary skill in the art.

Claims 1-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Laboureur et al. in view of Reedy et al. and Riggs or Neilsen et al.

Laboureur et al. teach the isolation of the A.flavus urate oxidase and the medical uses of the protein. They do not teach the expression of the urate oxidase gene from A. flavus.

Reedy et al. teach the isolation of the urate oxidase gene from a rat. In this teaching Reedy et al. also provide a general protocol for isolating the gene that encodes any urate oxidase protein.

Riggs teaches the expression of any heterologous protein

that is encoded by an isolated gene by use of that isolated gene in E. coli.

Neilsen et al. teach the expression of a heterologous protein that is encoded by an isolated gene by use of that isolated gene in COS-7 cells.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to make A. flavus urate oxidase in large quantities and high purity by expressing the A. flavus urate oxidase gene as taught by Neilen et al. or Riggs that had been isolated as taught by Reedy et al. from A. flavus as it is well known in the art that recombinant protein expression can result in highly pure proteins in high yield.

The combination of the above references is motivated as it has also been shown that A. flavus urate oxidase performs a useful enzymatic reaction. Large amounts of urate oxidase therefore would have been known to be useful as enzymes to perform medically useful enzymatic reactions to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Schmickel whose telephone number is (703) 308-4206.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

David B. Schmickel Ph.D.

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
ART UNIT 187 1814